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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,649	10/26/2001	Michael W. Dahm	24741-1529	5173
7590	05/18/2006		EXAMINER	
Patricia D. Granados Heller Ehrman White & McAuliffe 1717 Rhode Island Avenue, N.W. Washington, DC 20036-3001			CANELLA, KAREN A	
			ART UNIT	PAPER NUMBER
			1643	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/890,649	DAHM ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Karen A. Canella	1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 36-48 and 51-86 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) 36-48 and 51-86 is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
     Paper No(s)/Mail Date 4/13/09
- 4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 24, 2005 has been entered.

Claim 77 has been amended. Claim 87 has been canceled. Claims 36-48 and 51-86 are pending and under consideration.

Sections of title 35, U.S. Code not found in this action can be found in a prior action.

Claim 76 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "said lower compartment" lacks proper antecedent basis in claim 64.

Claims 36-48, 51-63 and 71-86 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a centrifugation vessel comprising a porous barrier, filter sieve or the flap as described in Figure 3 of the instant invention, does not reasonably provide enablement for a centrifuge vessel comprising any other type of "flap". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the centrifuge vessel of the invention commensurate in scope with these claims.

The instant method and product claims are dependent in part or in whole on a centrifugation vessel having a flap by which to divide the vessel into an upper and lower compartment. The specification teaches that the flap is closed in the state when the vessel is at rest ad opened by centrifugal force during centrifugation. During the course of centrifugation, cells within the applied body fluid migrate to a specific density within the fluid of the lower compartment. In order to isolate said cells after centrifugation, it is necessary that the gradient

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established by centrifugal force not be disturbed by a mechanical action of a flap closure as the tube is decelerated. The specification provides a drawing of such a mechanical closure and terms it a “flap”. One of skill in the art could not make a centrifugal vessel having a generic “flap” with a different geometry from that portrayed in figure 3, because to do so would cause a mechanical interference with the gradient formed by the centrifugation. In case of the disclosed “flap” the movement of the closure would be parallel to the plane of the band having the concentrated cells, and would not disrupt the cells. given the teachings of the specification, one of skill in the art would be subject to undue experimentation in order to make a centrifugation vessel with the broadly claimed “flap” which would function in the methods as claimed. In re Hyatt, 708 F.2d 712, 714-715, 218 USPQ 195, 197(Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). when the claims cover every conceivable structure for achieving the stated property of having a centrifugation vessel with a “flap”, while the specification discloses at most only those known to the inventor, a fact situation comparable to Hyatt is possible. (MPEP 2164.08(a))

Claims 64-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Suda et al (U.S. 4,391,802).

Claim 64 is drawn to a kit for the separation of tumor cells from a body fluid, comprising a cell separation medium which has a density in the range of 1.055 to 1.065 g/ml. Claim 65 embodies the kit of claim 64 further comprising a centrifugation vessel. Claim 66 embodies the kit of claim 64 wherein the medium has a density in the range of 1/059 to 1.061. Claim 67 embodies the kit of claim 64 wherein the medium has a density of about 1.060 g/ml. Claim 68 embodies the kit of claim 64 wherein the medium has a density of about 1.062 g/ml.

Suda et al disclose a cell separation medium and centrifugation vessel, wherein said medium has a density of 1.059, 1.054-1.059, and 1.059-1.064 (column 3, line 7 and line 11)

Claims 64 and 65 are rejected under 35 U.S.C. 102(e) as being anticipated by Jones et al (U.S. 6,051,393).

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Jones et al disclose a cell separation medium and centrifugation vessel, wherein said cell separation medium has a density of 1.055 (column 8, lines 57-60).

Claims 64, 65 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Asgari et al (U.S. 5,629,147).

Asgari et al disclose a cell separation medium and a centrifugation vessel, wherein said cell separation medium has a density of 1.065 (column 31, Table 10).

Claims 64-68, 70 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Vlasselaer et al (U.S. 5,474,687).

Van Vlasselaer et al disclose a Percoll cell separation medium having a density of 1.0605, plus or minus 0.00005 g/ml in the bottom of a cell-trap tube with body fluid in the upper portion of said tube (column 13, lines 32-52).

Claims 64, 65, 68 and 69 are rejected under 35 U.S.C. 102(e) as being anticipated by Mond et al (U.S. 5,932,427).

Mond et al disclose a cell separation medium and a centrifugation vessel, wherein said cell separation medium has a density of 1.062 (column 14, lines 13-17).

Claims 36-38 and 51-55 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27, 28, 29, 30, 31, 48 and 49 of U.S. Patent No. 6, 821, 726 in view of Van Vlasselaer et al (U.S. 5,474,687).

An obviousness-type double-patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g. In reBerg, 140 F.3d, 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

The instant claims are an obvious variant over the claims of '726 because Van Vlasselaer et al teach that having a barrier between the cell separation medium and blood is an improvement over prior art methods because it increases the recovery of separated cells because

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the desired cells can be decanted rather than removed by a pipette. Thus, one of skill in the art would reasonably conclude that the instant claims are obvious over the reference claims. One of skill in the art would be motivated to use the instant methods requiring a centrifugation vessel having a porous barrier, filter, sieve or flap, because it would provide a higher yield of the separated tumor cells in view of the teachings of Van Vlasselaer et al.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

5/13/2006

  
KAREN A. CANELLA PH.D  
PRIMARY EXAMINER